

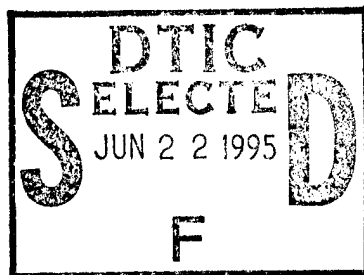
AL/CF-TR-1995-0060



**TEST AND EVALUATION OF THE BIRD PRODUCTS, CORP
BIRD AVIAN PORTABLE VENTILATOR
(MILITARY VERSION) MODEL 15300**

Butch O. Blake, TSgt, USAF

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Crew Technology Division
2502 Gillingham Dr. Suite 25
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May 1995

Final Technical Report for Period April 1994 - July 1994

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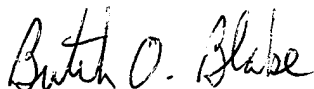
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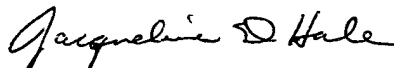
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This report has been reviewed and is approved for publication.



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TESTING AND EVALUATION OF THE BIRD PRODUCTS CORPORATION BIRD AVIAN PORTABLE VENTILATOR [MILITARY VERSION] MODEL 15300

BACKGROUND

Defense Logistics Agency requested assessment of the Bird Avian Portable Ventilator for possible triservice use. This was a collaborative effort with United States Army Aeromedical Research Laboratory (USAARL) and Armstrong Laboratory to eliminate unnecessary duplication of testing. USAARL performed testing required for rotary-wing aircraft and forwarded all test results to Armstrong Laboratory for assessment in meeting fixed-wing aeromedical aircraft requirements.

DESCRIPTION

The Bird Avian Portable Ventilator, Model 15300, hereinafter referred to as Bird Avian, is a portable, electronically controlled, time or volume-cycled, pressure-limited ventilator (Fig. 1). It can support a variety of ventilation modes: CONTROL, ASSIST/CONTROL and SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION (SIMV). The Bird Avian is microprocessor controlled and provides the operator with a variety of controls and comprehensive alarms including: Automatic apnea backup ventilation, 0-100 Liter Per Minute (LPM) peak flow, 0-150 Breath Per Minute (BPM), 10-100 cmH₂O peak inspiratory pressure, Proximal airway pressure monitoring, and Audio/Visual alarms for High/Low peak pressures, apnea, inverse inspiratory/expiratory (I:E) ratio, and patient circuit disconnect. It has a durable exterior, is compact, light weight, and easy to transport and store. The Bird Avian has its own internal rechargeable battery, 115/230 VAC, 50-400 Hz multivoltage switch selectable AC power supply and 12 VDC power cable to allow for connection to external 11-30 VDC positive or negative ground power sources. The battery pack may be recharged within the range of either of the aforementioned AC or DC voltages. The Bird Avian operates from gas sources capable of delivering 40-60 PSIG. These include compressed gas cylinders (air, oxygen, or air/oxygen mixtures), medical grade air compressors, and PTLOX or on-board aircraft gas sources. The Bird Avian can also accept blended gas mixtures from a gas blender. Positive End Expiratory Pressure (PEEP) may be used in all modes of operation. See Appendix A for size & weight specifications. The Bird Avian comes in a carrying case with the following components: external multivoltage AC power supply, 12 VDC power cables (1 with cigarette lighter plug, 1 with undetermined end [no plug]), reusable patient exhalation valve, 6 ft of oxygen source supply hose (green), 6 ft of air source supply hose (yellow), reusable PEEP valve, 6 ft of 15mm Patient Gas Source Supply hose, two 6 ft lengths of 1/8" tubing, and two Commercial Operating Instruction/Maintenance Manuals.

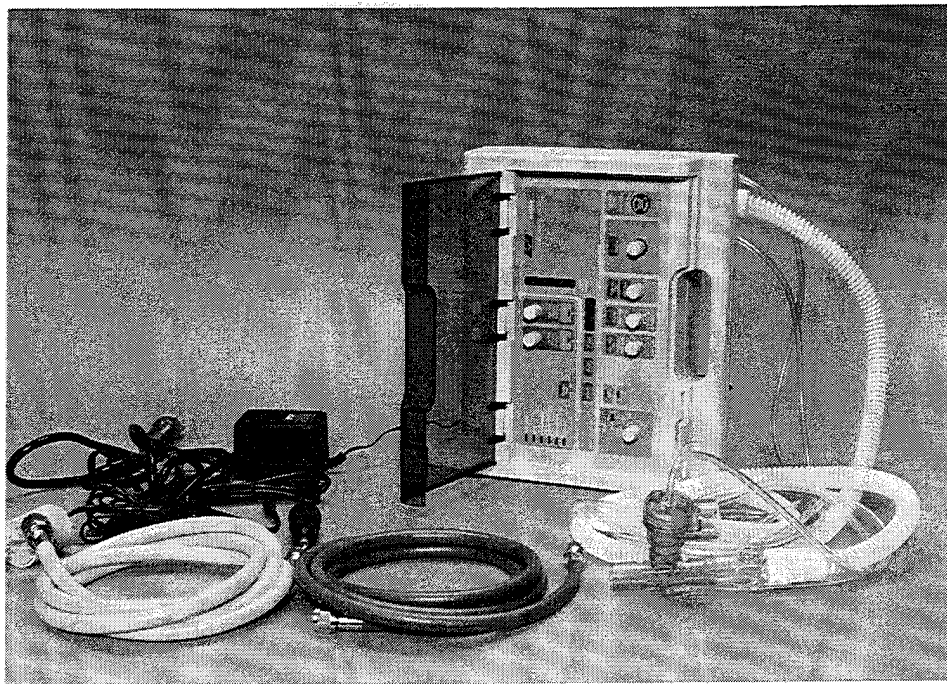


Figure 1. Bird Avian Portable Ventilator, Model 15300.

METHODS

Test methods and performance criteria were derived from various military standards (See References 1,2), nationally recognized performance guidelines, Bird Avian portable ventilator Operator Instructions and Maintenance Manual (3), Emergency Care Research Institute (ECRI) (4), and Aeromedical Research Procedures Guide (5).

Test Setup

The ventilator was connected to a Bio-Tek Instruments Model VT-2 Ventilator Tester, employing the patient breathing circuit provided by the manufacturer. This breathing circuit was used throughout our evaluation. An Airdyne air compressor was connected to the gas inlet port on the Bird Avian. The power cord was plugged into an AC wall outlet and corresponding "EXTERNAL POWER" receptacle on the unit. The ventilator controls were set as follows: Flow Knob @ 50 lpm; Tidal Vol. @ 800 ml; Breath Rate @ 16 BPM; Insp. Time 2.1 sec; Man. PEEP Rel. / Assist Sensitivity @ -.2; Mode @ Control; High Peak Pressure (cmH₂O) @ 70; Low Peak Pressure (cmH₂O) @ 10; Sigh and Manual Breath OFF. The VT-2 ventilator analyzer settings were as follows: Resistance @ 20; Compliance @ .05 L/cmH₂O; pressure units in centimeters

of water; Relative Humidity @ 50%; Atmospheric Pressure @ ground-level testing set for 747 mmHg (during altitude testing the VT-2 was reset to correspond to the atmospheric pressure at each test position); and Gas temperature 25°C.

Performance Checks

The following measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. The Bio-Tek VT-2 ventilator analyzer's Full Test was used to measure and record 15 parameters. The Full Test mode includes the following: breath rate, inspiratory to expiratory ratio (I:E ratio), tidal volume, minute volume, inspiratory time, inspiratory hold time, expiratory time, expiratory hold time, cycle time, peak airway pressure, peak lung pressure, end expiratory pressure, mean airway pressure, inspiratory flow, and expiratory flow.

Three Full Tests were performed and recorded at 5-minute intervals, before and after each laboratory test. During each laboratory test a Full Test was done and the parameters were recorded. Values derived from the 3 pretest recordings were used as a baseline reference in determining variation in results during each portion of testing. Post-performance check values were used to identify any deviation from the pre-performance check that might indicate damage to the ventilator as a result of testing.

Battery Performance Test

The 12 VDC internal battery is rated for approximately 11 hours of operation and has a recharge time of 14 - 16 hours. Continuous charging is permissible with the 12 VDC power cable and the 115-220 VAC/60-400Hz multivoltage switch selectable power supply.

From a full charge, the Bird Avian operated on battery power until the Battery Low / Fail Alarm activated. The unit was turned off and the battery was charged on 115VAC/60Hz power. After recharging for 24 hours, the unit was run on battery power until the Battery Low / Fail Alarm activated. The same procedure was repeated utilizing 115VAC/400Hz and 28VDC power to recharge the battery. Documentation was recorded on the battery charge and operation time.

Altitude

The Bird Avian was tested to see the effects of reduced barometric pressure in the Armstrong Laboratory hypobaric chambers located in Bldg. 160, Brooks AFB, TX. The testing consisted of operating the Bird Avian while connected to the Bio-Tek VT-2 Ventilator Analyzer, stopping at 2,000 ft intervals up to 10,000 ft to ensure its continued operation and compliance with prescribed operating parameters. The VT-2

transducers were zeroed at each stop and atmospheric pressure readings were changed to record the current pressure. The ventilator was given time to stabilize at each altitude and 3 Full Tests were accomplished at 5-minute intervals.

Rapid Decompression

The purpose of this test was to approximate the stress that medical equipment is exposed to during normal, emergency, and accidental decompression. Although, rapid decompressions are uncommon in military transport aircraft, the effect of such an occurrence on a medical item could present a severe safety hazard to the patient, crew, or aircraft operations.

Protocol involves ascending to 8,000 ft at a minimum of 5,000 ft per minute, then decompressing to 40,000 ft in 60 seconds while observing equipment performance. The chamber was returned to ground level and three Full Tests were accomplished. This test was repeated for 7- and 1-second rates of decompression. The ventilator was placed inside the test chamber and connected to a Manley Lung simulator utilizing the same settings as used for the performance check. Visual observation of the pressure gauge was done through a window to monitor maximum pressure delivered at the time of decompression. The VT-2 remained outside the test chamber and was employed to obtain test data at the end of each RD.

Airborne Feasibility

Inflight feasibility tests were conducted to develop and/or verify medical equipment operating procedures and to validate operational performance of the equipment in the actual aeromedical evacuation environment. Inflight testing was conducted on the C-9A aircraft. Oxygen from the on board therapeutic system on the C-9A was attached to the ventilator, providing 50 ± 5 psi. The Bird Avian was powered utilizing the aircraft's 115VAC/60 Hz power supply.

Setup and securing methods, integration with aircraft oxygen and electrical systems, and use and storage of the carrying case was evaluated. Medical crew was encouraged to participate in the evaluation and their comments were documented and included in the evaluation.

RESULTS

Initial testing of the Bird Avian was conducted by the United States Army Aeromedical Research Laboratories (USAARL), located at Fort Rucker, Alabama (6). Test results from USAARL were reviewed and found acceptable to meet our standards for vibration, electrical safety, and environmental factors. The Bird Avian exceeded the Air Force thresholds outlined in MIL-STD-461D for electromagnetic interference (EMI).

We submitted USAARL EMI test results to ASC/ENAI at Wright-Patterson AFB for evaluation. ASC/ENAI granted waiver approval for use only on large-bodied aircraft. EMI testing has shown the unit may interfere with VHF/FM and HF frequencies due to excessive radiated emissions. (See Attachment 1.)

Battery Performance

The Bird Avian passed battery performance testing with unit lasting according to manufacturers' guidelines.

Altitude

Altitude testing identified a 29% increase of the preset tidal volume (V_t) while ascending to 10,000 ft. Upon returning to ground level the tidal volume returned to preset value. The graph below shows the rise in tidal volume while ascending and descending in altitude (Fig. 2).

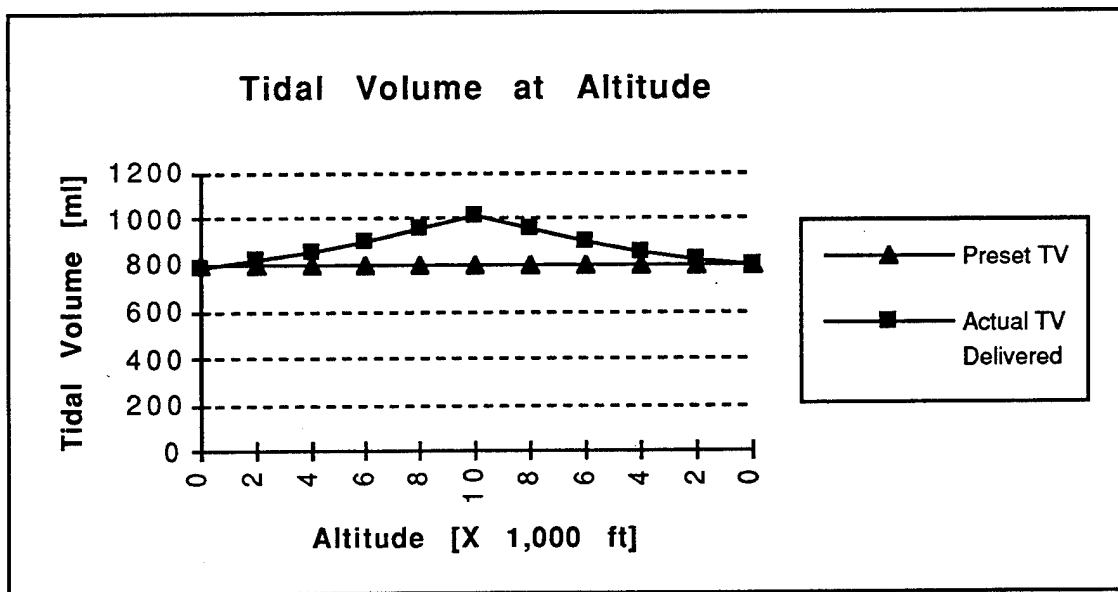


Figure 2. Tidal Volume at Altitude.

Rapid Decompression

During this series of tests, the settings dialed into the Bird Avian were the same used in the baseline performance check. The PEEP valve was placed in the circuit at

the exhalation end without any value dialed in. In all three tests the Bird Avian went above the preset High Peak Pressure alarm setting of 70 cmH₂O. The PEEP valve's internal diaphragm stuck in the fully closed position, causing back pressure into the patient breathing circuit. This pressure continually inflated the test lung not allowing air to escape through the exhalation port.

A second Rapid Decompression series was accomplished without the PEEP valve placed in the patient circuit. The High Peak Pressure was set to alarm at 100 cmH₂O. The rest of the settings were the same as in the baseline performance check. Upon decompressing the chamber, the Bird Avian exceeded the 100 cmH₂O limit by approximately 10 cmH₂O in all aspects of testing. Our evaluation found the Bird Avian within acceptable limits for Rapid Decompression testing.

Airborne Feasibility

This evaluation confirmed that the Bird Avian ventilator will successfully function on the C-9A, C-130, and C-141, provided special adapters accompany equipment for proper set-up. Below is a detailed summary for each aircraft. The Bird Avian was easy to enplane and deplane on each of the aircraft. It is compatible with the electrical systems used on each aircraft.

C-9A: An oxygen hose with a Schrader adapter at one end and a female adapter at the other end is needed for obtaining oxygen from a C-9A wall mount oxygen source. Visual alarms could only be seen if a crew member were standing over the unit. Audible alarms could be heard at approximately 6 to 8 feet away. When moving a patient on a ventilator, it will be necessary to have a transportable oxygen source. We evaluated two methods of securing the Bird Avian to a standard NATO liter (Figs. 3 & 4).

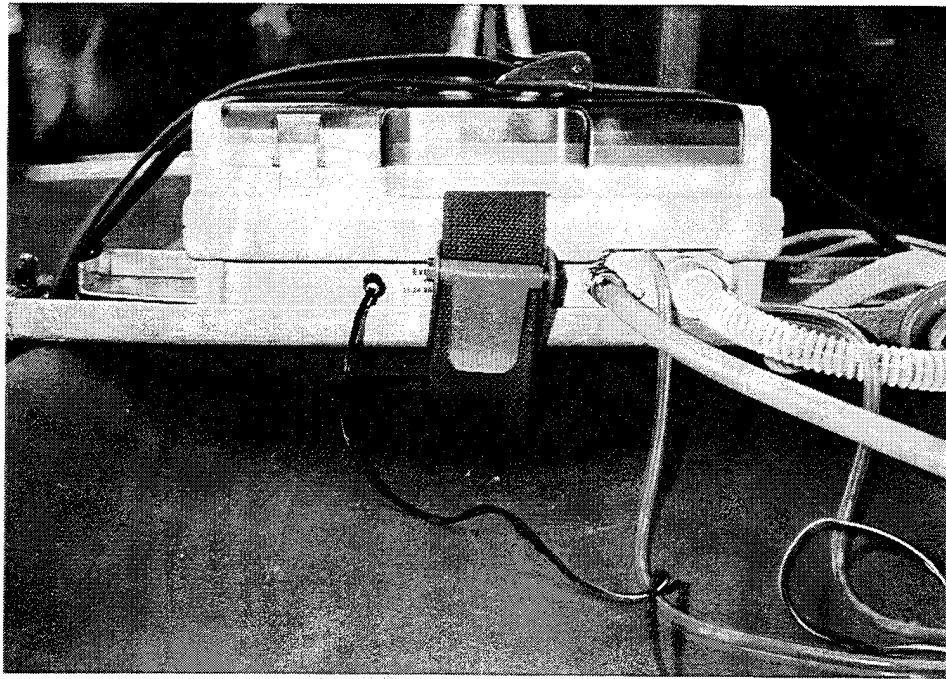


Figure 3. Secured to NATO Litter with Litter Brackets.

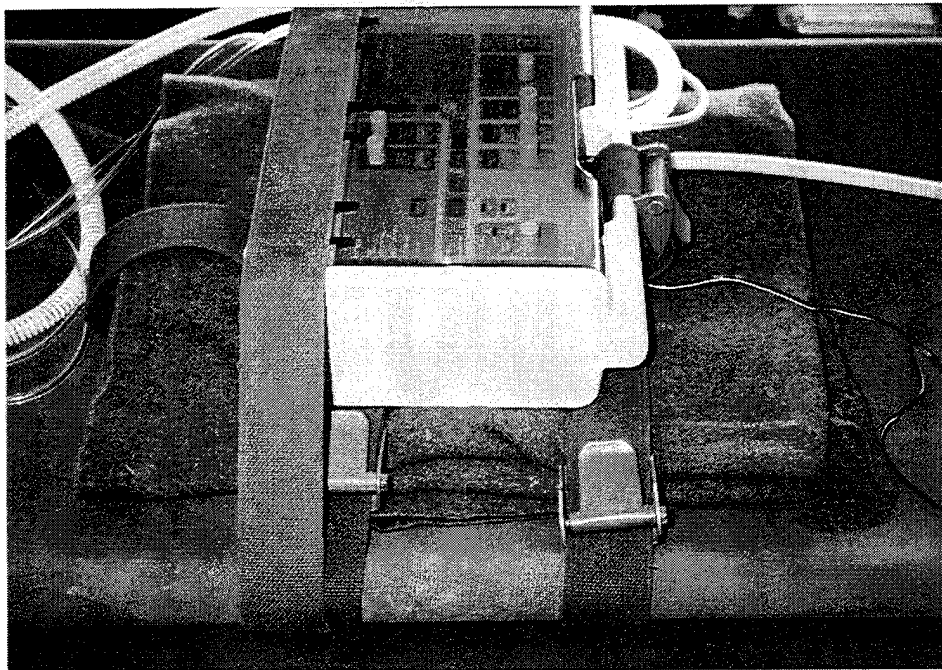


Figure 4. Secured with NATO Litter Straps and Blanket for Support.

C-130/C-141: Additional human factors for inflight use were observed on mock-up aircraft. The PTLOX can provide the necessary oxygen source on board the aircraft. The standard PTLOX oxygen hose will interface with the Bird Avian. On the C-141, the Bird Avian will require an oxygen hose that has a female adapter at each end to be compatible with the C-141 oxygen system. This oxygen hose with dual female adapters is provided by Bird Corp. We tested several different methods of securing the unit on board the aircraft. If the Waters bracket (AL-TR-1992-0086) is utilized, the unit can be positioned facing a crew member; however, the unit will have limited access and cause some stress to lines and hoses (Fig. 5). On the C-130 & C-141 the audible alarms can only be heard at an approximate 8 ft distance. If unit is placed in the upright position and secured to standard NATO litter or Waters Bracket, the unit must be placed below chest level to adequately observe functional controls.

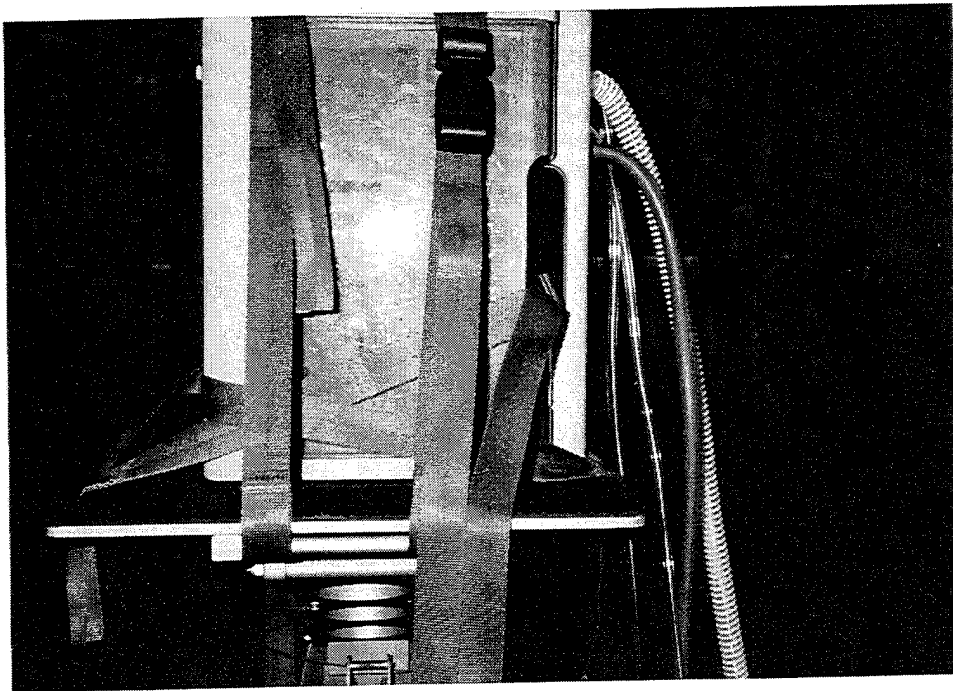


Figure 5. Secured to WATERS Bracket on C-130 Litter Stanchion.

General observations:

1. Unit placement is restricted by constraints of ventilator tubing.
2. When securing with litter straps, observation of the control panel by crew and access to control knobs is blocked by the straps.
3. The 15 mm spiral hose, is smaller than the current patient tubing used in the aeromedical evacuation system. Current ventilator tubing is too large and may not fit the To Patient port. (Disposable tubing is available from Company.)
4. The patient valve is **not** disposable and must be sterilized after use.
5. Adapters are needed for addition of any special equipment inline with the ventilator tubing, i.e., Mini-Ox III, temperature gauge, heat-moisture exchanger.

6. Special equipment is needed for oxygen interface, i.e., low-pressure oxygen hose with a Schrader adapter.

CONSIDERATIONS

In consulting with the Respiratory Therapy Department, Wilford Hall Medical Center, several items of interest were discussed. We asked their expertise on what additional equipment would be required to transport a patient on an extended flight. In addition to the standard patient breathing circuit, a heat-moisture exchanger (HME) and a hand-held respirometer should be included. Since the ventilator increases the tidal volume delivered to the patient while at altitude, the respiratory technician would require a respirometer to verify patient volume delivery and make adjustments to the unit as appropriate. The respirometer is usually carried by the technician who is accompanying the patient. If the patient requires blended air, a pulse oximeter could be used to monitor the patient's FI_{O_2} , instead of using the Mini-Ox III in line. This would avoid the requirement for adapters.

The respiratory therapy personnel noted some problems with cleaning of the patient valve by heat sterilization. Hazing of the patient valve occurred causing stress fractures and weakness around attachment ports. They also noted that the mushroom valve located inside the patient valve can be screwed both up and down, and, if improper placement should occur, it may cause an artificial peep or block off air delivery to the patient. This valve should be checked for proper placement prior to each patient use.

RECOMMENDATIONS

1. A heat-moisture exchanger be used for maintaining airway humidification.
2. Respiratory technician is required to monitor tidal volume while inflight to adjust unit appropriately.
3. The following notes and warnings be added in the Operator Instruction and Maintenance Manual.
 - a. **NOTE:** Repeated heat sterilization of the patient valve may cause hazing and deterioration of the valve. Careful inspection should be accomplished prior to patient use to ensure all attachment ports will withstand use. Recommend liquid agents or ethylene oxide (ETO) gas for sterilization.
 - b. **WARNING: Restricted for use on USAF large-bodied cargo aircraft only.** The pilot and crew should be notified when the equipment is in use.
 - c. **WARNING LABEL** attached on unit: **The ventilator is to be operated on battery power for take-off and landings.**
4. The items listed below were not found in complete compliance with MIL-STD-1472D.
 - a. Change the color red now being used for normal operating indicators. Use red for alarm indicators only.

- b. Provide better access to all ports: Gas Inlet, Exhalation Drive, To Patient, and Airway Pressure to accommodate the use of Nomex flight gloves, which is required on various aeromedical evacuation flights. Both identification and accessibility are restricted due to close proximity with each other. Labeling of ports should be color contrasted against background for clear identification.
 - c. Front Panel does not allow the user to read controls and indicators without tilting head to one side when the unit is placed in the upright position or when the unit is secured to a NATO litter or WATERS Bracket. To prevent head tilt, place controls and indicators in a more effectively ergonomic position.
 - d. Bird Avian's internal fuse is not easily accessible for replacement. Provide an access port or door to allow the fuse to be changed.
 - e. Increase the distance between the Control Knob, Tidal Volume touch membrane and Insp. Time touch membrane to prevent accidental value change.
5. Suggest incorporating securing brackets to the Bird Avian that will allow it to be secured to aircraft litter stanchion poles and NATO litters.

CONCLUSION

Overall, the Bird Avian Portable Ventilator [Military Version] model 15300 is considered airworthy. It operates within expected parameters at altitude and does not produce a hazard to patient or crew during rapid decompression. When used on battery power the Bird Avian passed EMI testing; however, the unit is restricted for use on USAF large-bodied aircraft. However, several human factor concerns should be addressed prior to use in USAF aeromedical evacuation missions. See Recommendations this report.

REFERENCES

1. MIL-STD 461-D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference, Category A1e.
2. MIL-STD 810-E, Environmental Test Methods and Engineering Guidelines.
3. Bird Products Corp. Operator Instructions & Maintenance Manual.
4. Emergency Care Research Institute (ECRI), INDEX 1993.
5. Aeromedical Research Procedures Guide, Internal Operating Instruction, Armstrong Laboratory, Systems Research Branch.
6. Published report #94-24 (May 1994) U.S. Army Aeromedical Research Laboratory, Ft. Rucker, Alabama.

APPENDIX A

SPECIFICATIONS AND OPERATING FEATURES OF THE BIRD AVIAN PORTABLE VENTILATOR [MILITARY VERSION] MODEL 15300

Model: Bird Avian model 15300

Manufacturer: Bird Products Corp.
1100 Bird Center Dr.
Palm Springs, CA. 92262

Operating Modes: CONTROL-with/without (PEEP), with/without SIGH
ASSIST-CONTROL-with/without (PEEP), with/without SIGH
SIMV-with/without (PEEP), with/without SIGH

Inspiratory Time: Adjustable, 0.1 to 3.0 Seconds

Tidal Volume: Adjustable, 50 to 2,000 ml

Breath Rate: Adjustable, 0 to 150 BPM

Flow: Adjustable, 0 to 100 LPM

Assist Sensitivity: Adjustable, -2 to -8 cmH₂O

Manual PEEP Reference Set: Adjustable, 0 to 20 cmH₂O

Pressure Relief: Adjustable, Preset @ 100 H₂O

Sigh: On/Off 1 sigh/100 breaths or 7 minutes
1.5 X Inspiratory Time (3.0 seconds max.) or Tidal Volume (2,000 ml
max.) setting
High Pressure Limit 1.5 X setting (100 cmH₂O max.)

Manual Breath: Touch button activated. When depressed a continuous flow of gas will be delivered and will stop when the button is released. This also functions during a CPU failure.

PEEP/CPAP: 0 to 20 cmH₂O (with removable PEEP valve)

Display Controls (Push-to-Display): Breath Rate, Insp. Time, Tidal Vol., Assist Sensitivity, High Peak Pressure Alarm, and Low Peak Pressure Alarm.

Alarm Indicator Lamps: High Peak Pressure (15 to 100 cmH₂O)
Low Peak Pressure (OFF, 2 to 50 cmH₂O)
I:E Ratio [inverse] (Audio/Visual)
Apnea (Audio/Visual)
External Power - Low & Fail (Audio/Visual)
Disconnect (Audio/Visual)
PEEP Not Set (Audio/Visual)
Battery Low/Fail (Audio/Visual)
Alarm Silence/Reset (Variable Duration - Depending on the
alarm - Single Touch Button)

Digital Bar Graph: Displays Airway Pressure range -10 to 100 cmH₂O

Operating Voltages: External DC Power (External Input Voltages 11 to 30 VDC
[Positive or Negative Polarity])
Internal Battery - Rechargeable (11 Hours minimum operation on
full charge)
External Power Adapter (Switch selectable input) 100 - 125
VAC, 50 - 400 Hz / 220 - 250 VAC, 50 - 400 Hz.

Multivoltage switch selectable AC power supply, weight 2 pounds (.91 Kg)

Pneumatics: 40 to 60 psig of clean, dry medical grade air, oxygen or air-oxygen
mixtures. INPUT SOURCE: Compressed gas cylinders, Medical grade air
compressors, On-board aircraft gas sources, and Blended gas mixtures from a gas
blender.

Size: 10 Inches (254mm) High X 12 Inches (305mm) Wide X 5 Inches (127mm) Deep

Weight: 9.8 Pounds (4.45 Kg)

Temperature Ranges: Operating: -4°F to 115°F (-20°C to 46°C)
Storage: 50°F to 80°F (10°C to 27°C)



DEPARTMENT OF THE AIR FORCE

HEADQUARTERS AERONAUTICAL SYSTEMS CENTER (AFMC)
WRIGHT-PATTERSON AIR FORCE BASE, OHIO

25 Jun 94

MEMORANDUM FOR AL/CFTS

KINDRA A. LARSON
2504 D DRIVE SUITE 1
BROOKS AFB TX 78235-5104

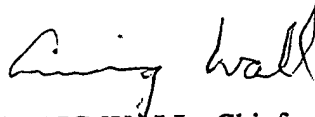
FROM: ASC/ENAI
Building 20
2450 D Street Suite 2
Wright-Patterson AFB OH 45433-7630

SUBJECT: Review Electromagnetic Interference (EMI) Test Results For The Bird Avian Ventilator

1. We have reviewed the subject data and recommend using the ventilator on large body aircraft only, and during take off and landing (below 10,000 ft.) the ventilator should be operated on batteries. We recommend this because the ventilator meets AF radiated emission requirements (RE02) when operated on internal battery. The ventilator can operate on 60 Hz, 400 Hz, or 28vdc during other phases of flight. The ventilator has emission in excess of MIL-STD-461 limits when powered externally. These emissions will not cause any degradation to flight safety and mission capability should not be affected for the large body aircraft. The pilot and crew should be aware that the equipment is being operated.
2. The RE02 test data reflects the limits imposed in MIL-STD-461A Notice 4 (Army notice). The Army's RE02 requirements are 10 dB more stringent than the Air Force's requirements levied for test method RE02 in MIL-STD-461A, B, C, or D.
3. The RF noise generated by the ventilator is not a concern for any onboard equipment other than antenna connected receivers (highly sensitive and intentional apertures -- antennae). The RF noise generated by the ventilator is in the frequency range of 7 MHz to 24 MHz, which covers three fourths of the HF radio band. Ten HF channels, out of fourteen hundred, may be affected. There are no navigational receivers in this frequency range.
4. The radiated susceptibility (RS03) results identified thresholds at 8.6 volts/meter or better in the 180 MHz to 600 MHz frequency range, with the rest of frequency range meeting MIL-STD-461 requirements. Aircraft transmitters in this frequency range, for the aircraft listed in your letter, typically are not high powered. For cargo aircraft we would rarely expect to see field strengths that exceed 8 volts/meter in the cargo bay. In those instances where high-powered ground emitters illuminate the aircraft, it is only for a very short time due to aircraft

movement and/or the search pattern of the emitter. Exposures to high level RF energy will normally occur during take off and landing (below 10,000 ft.). Despite the severity of the electromagnetic environment, there have been relatively few operational problems (ref. MIL-STD-1818). If you can operate under the constraints that the ventilator may (very low probability) experience temporary *interference*, then we recommend that you use it. The term "interference" is ambiguous since the criteria for susceptibility (Army test report dated Oct. 93) are not defined in the test report (I was unable to obtain the susceptibility criteria from the test agency or user).

4. For additional information Steven Coffman at DSN 785-5078 or (513) 255-5078.



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